State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

* The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
* Please address questions regarding information on this notice to the agency.
* The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
* The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
State Admin Rule Filing Id:		Time filed:	

		Agency No.		Rule No.		Section No.
Utah Admin. Code Ref (R no.):	**R**	156	-	37	-	
Changed to Admin. Code Ref. (R no.):	**R**		-		-	

1.	**Agency:**	Commerce/Division of Occupational and Professional Licensing		
	Room no.:			
	Building:	Heber M. Wells Building		
	Street address 1:	160 East 300 South		
	Street address 2:			
	City, state, zip:	Salt Lake City UT 84111-2316		
	Mailing address 1:	PO Box 146741		
	Mailing address 2:			
	City, state, zip:	Salt Lake City UT 84114-6741		
	Contact person(s):			
	Name:	**Phone:**	**Fax:**	**E-mail:**
	Rich Oborn	801-530-6767	801-530-6511	roborn@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2.	**Title of rule or section** (catchline)**:**
	Utah Controlled Substances Act Rule
3.	**Type of notice:**
	New ___; Amendment XXXX; Repeal ___; Repeal and Reenact ___
4.	**Purpose of the rule or reason for the change:**
	S.B. 55 and S.B. 138 were passed during the 2014 General Legislative Session. S.B. 55 created a new license classification within the Pharmacy Practice Act (Title 58, Chapter 17b) for dispensing medication practitioner clinic pharmacies. S.B. 138 amended the Controlled Substances Act (Title 58, Chapter 37) to allow a prescriber to include more than one prescription of a controlled substance per prescription form. Various rule amendments are necessary due to these statutory revisions. Other rule amendments are being proposed at the request of the Board of Pharmacy.
5.	**This change is a response to comments from the Administrative Rules Review Committee.**
	No XXX; Yes ___
6.	**Summary of the rule or change:**

	The following rule amendments are made throughout R156-37: updating of references, renumbering of paragraphs, and minor grammatical and stylistic changes. Section 301: Amendments to Subsection (1) are necessary due to S.B. 55. Other amendments are necessary due to recent amendments to R156-17b. Section 302: Subsection (2)(b) is unnecessary because employees of animal control facilities are exempted from controlled substance licensure in R156-37-305(4). Section 304: This section is removed because the Board of Pharmacy and other licensing boards requested that the controlled substance examination no longer be required. Section 305: Subsection (1) is removed because this exemption was moved to Subsection (3). In Subsection (2), individuals and entities engaged in research using pharmaceuticals within a university research facility are exempt from controlled substance licensure. The Board of Pharmacy supports this amendment primarily because S.B. 14 passed in the 2013 General Legislative Session exempted these individuals and facilities from pharmacy and pharmacist licensure. In Subsection (4), individuals employed by a facility engaged in certain activities are exempted from controlled substance licensure. An individual may qualify for this exemption as long as the facility employing that individual has obtained a controlled substance license, has obtained a Drug Enforcement Administration (DEA) registration number, and uses the controlled substances according to a written protocol. Section 603: Subsection (3) is removed due to S.B. 138. Section 606: Subsection (1)(b) is removed because the Division no longer authorizes licensees to dispose of controlled substances in the manner described in this subsection.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	Affected: No ___; Yes XXX
	Proposed amendments to R156-37-305(2) and (3) grant controlled substance license exemptions to certain individuals and entities. The Division is unable to estimate the number of individuals and entities that will no longer be required to submit a license application due to this amendment; however, the Division will experience a cost impact of $100 per initial license application and $78 per license renewal application that is not submitted. Removing the exam requirement in Section 304 does not have a cost impact on the Division because this is a true or false open-book exam that is part of the license application. The Division has never collected a fee for this exam.
	B) Local government:
	Affected: No XXX; Yes ___
	The proposed amendments apply only to certain licensees and applicants for a controlled substance license. As a result, the proposed amendments do not apply to local governments.
	C) Small businesses ("small business" means a business employing fewer than 50 persons)**:**
	Affected: No ___; Yes XXX
	Proposed amendments to R156-37-305(2) and (3) grant controlled substance license exemptions to certain entities. The Division is unable to estimate the number of entities that will no longer be required to submit a license application due to this amendment; however, impacted entities will experience a cost savings of $100 per initial license application and $78 per license renewal application that is not submitted.
	D) Persons other than small businesses, businesses, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency)**:**
	Affected: No ___; Yes XXX
	Proposed amendments to R156-37-305(2) and (3) grant controlled substance license exemptions to certain individuals. The Division is unable to estimate the number of individuals that will no longer be required to submit a license application due to this amendment; however, impacted individuals will experience a cost savings of $100 per initial license application and $78 per license renewal application that is not submitted.
8.	**Compliance costs for affected persons:**
	Proposed amendments to R156-37-305(2) and (3) grant controlled substance license exemptions to certain individuals. The Division is unable to estimate the number of individuals that will no longer be required to submit a license application due to this amendment; however, impacted individuals will experience a cost savings of $100 per initial license application and $78 per license renewal application that is not submitted.
9.	**A) Comments by the department head on the fiscal impact the rule may have on businesses:**

	In addition to making technical corrections, this filing expands the list of persons who may be licensed to deal with controlled substances; eliminates an examination requirement from the licensing process; deletes a provision (prohibiting a prescriber from including more than one controlled substance on a single prescription form), which has become moot due to legislative action; and deletes language describing a controlled substance disposal method that the Division no longer approves. It is not anticipated that this filing will pose any fiscal impact to businesses. Any savings that businesses might realize from being permitted to use a single prescription form for multiple controlled substances will be minimal, as will any costs that might attend a business's being minimally restricted in its methods of drug disposal.
	B) Name and title of department head commenting on the fiscal impacts:
	Francine A. Giani, Executive Director

10. **This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.**
State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) **:**

Subsection 58-1-106(1)(a)	Subsection 58-37-6(1)(a)
Subsection 58-37f-301(1)	

11. **This rule adds, updates, or removes the following title of materials incorporated by references** (a copy of materials incorporated by reference must be submitted to the Division of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation	**Second Incorporation**
Official Title of Materials Incorporated (from title page)		
Publisher		
Date Issued		
Issue, or version		
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference		
Action: Adds, updates, or removes		

(If this rule incorporates more than two items by reference, please attach additional pages)

12. **The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**		02/17/2015
B) A public hearing (optional) will be held:		
On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**
01/20/2015	8:30 AM	160 East 300 South, Conference Room 210 (2nd floor), Salt Lake City, Utah

13. **This rule change may become effective on** (mm/dd/yyyy)**:** 02/24/2015

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid"); may not include the name of the agency**:**	
	controlled substances	licensing

15.	**Attach an RTF document containing the text of this rule change** (filename)**:**	R156-37.pro

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	Mark B. Steinagel, Director	**Date** (mm/dd/yyyy)**:**	12/18/2014

R156. Commerce, Occupational and Professional Licensing.
R156-37. Utah Controlled Substances Act Rule.
R156-37-301. License Classifications - Restrictions.

(1) Consistent with the provisions of law, the Division may issue a controlled substance license to manufacture, produce, distribute, dispense, prescribe, obtain, administer, analyze, or conduct research with controlled substances in Schedules I, II, III, IV, or V to qualified persons. Licenses shall be issued to qualified persons in the following categories:

(a) pharmacist;
(b) optometrist;
(c) podiatric physician;
(d) dentist;
(e) osteopathic physician and surgeon;
(f) physician and surgeon;
(g) physician assistant;
(h) veterinarian;
(i) advanced practice registered nurse or advanced practice registered nurse-certified registered nurse anesthetist;
(j) certified nurse midwife;
(k) naturopathic physician;
(l) Class A pharmacy-retail operations located in Utah;
(m) Class B pharmacy located in Utah providing services to a target population unique to the needs of the healthcare services required by the patient, including:
(i) closed door pharmacy;
(ii) hospital clinic pharmacy;
(iii) methadone clinic[~~s~~] pharmacy;
(iv) nuclear pharmacy;
(v) branch pharmacy;
(vi) hospice facility pharmacy;
(vii) veterinarian pharmaceutical facility pharmacy;
(viii) pharmaceutical administration facility pharmacy;[~~ and~~]
(ix) sterile product preparation facility pharmacy; and
(x) dispensing medical practitioner clinic pharmacy.
(n) Class C pharmacy [~~located in Utah~~]engaged in:
(i) manufacturing;
(ii) producing;
(iii) wholesaling;[~~ and~~]
(iv) distributing; and
(v) reverse distributing.
(o) Class D Out-of-state mail order pharmacies.
(p) Class E pharmacy including:
(i) medical gases provider[~~s~~];[~~ and~~]
(ii) analytical [~~laboratories~~]laboratory pharmacy;
(iii) animal control pharmacy;

(iv) human clinical investigational drug research facility pharmacy; and

(v) animal narcotic detection training facility pharmacy.

(q) Utah Department of Corrections for the conduct of execution by the administration of lethal injection under its statutory authority and in accordance with its policies and procedures.

(2) A license may be restricted to the extent determined by the Division, in collaboration with appropriate licensing boards, that a restriction is necessary to protect the public health, safety or welfare, or the welfare of the licensee. A person receiving a restricted license shall manufacture, produce, obtain, distribute, dispense, prescribe, administer, analyze, or conduct research with controlled substances only to the extent of the terms and conditions under which the restricted license is issued by the Division.

R156-37-302. Qualifications for Licensure - Application Requirements.

(1) An applicant for a controlled substance license shall:

(a) submit an application in a form as prescribed by the Division; and

(b) shall pay the required fee as established by the Division under the provisions of Section 63J-1-504.

(2) Any person seeking a controlled substance license shall[~~:~~ ~~(a)~~] be currently licensed by the state in the appropriate professional license classification as listed in R156-37-301 and shall maintain that license classification as current at all times while holding a controlled substance license[~~; or~~

~~(b) be engaged in the following activities which require the administration of a controlled substance but do not require licensure under Subsection (a):~~

~~(i) animal capture for transport or relocation as an employee or under contract with a state or federal government agency; or~~

~~(ii) other activity approved by the Division in collaboration with the appropriate board~~].

(3) The Division and the reviewing board may request from the applicant information [~~which~~]that is reasonable and necessary to permit an evaluation of the applicant's:

(a) qualifications to engage in practice with controlled substances; and

(b) the public interest in the issuance of a controlled substance license to the applicant.

(4) To determine if an applicant is qualified for licensure, the Division may assign the application to a qualified and appropriate licensing board for review and recommendation to the Division with respect to issuance of a license.

[~~**R156-37-304. Qualifications for Licensure - Examinations.**~~

~~Each applicant for a controlled substance license shall be required to pass an examination administered at the direction of the Division on the subject of controlled substance laws.~~]

R156-37-305. Exemption from Licensure - [~~Animal Euthanasia and~~]Law Enforcement Personnel, University Research, Narcotic Detection Training of Animals, and Animal Control.

In accordance with Subsection 58-37-6(2)(d), the following persons are exempt from licensure under Title 58, Chapter 37:

(1) [~~Individuals employed by an agency of the State or any of its political subdivisions, who are specifically authorized in writing by the state agency or the political subdivision to possess specified controlled substances in specified reasonable and necessary quantities for the purpose of euthanasia upon animals, shall be exempt from having a controlled substance license if the agency or jurisdiction employing that individual has obtained a controlled substance license, a DEA registration number, and uses the controlled substances according to a written protocol in performing animal euthanasia.~~

~~(2)~~]Law enforcement agencies and their sworn personnel are exempt from the licensing requirements of the Controlled Substance Act to the extent their official duties require them to possess controlled substances; they act within the scope of their enforcement responsibilities; they maintain accurate records of controlled substances [~~which~~]that come into their possession; and they maintain an effective audit trail. Nothing herein shall authorize law enforcement personnel to purchase or possess controlled substances for administration to animals unless the purchase or possession is in accordance with a duly issued controlled substance license.

(2) Individuals and entities engaged in research using pharmaceuticals as defined in Subsection 58-17b-102(65) within a research facility as defined in Subsection R156-17b-102(49).

(3) Individuals employed by a facility engaged in the following activities if the facility employing that individual has a controlled substance license in Utah, a DEA registration number, and uses the controlled substances according to a written protocol:

(a) narcotic detection training of animals for law enforcement use; or

(b) animal control, including:

(i) animal euthanasia; or

(ii) animal immobilization.

R156-37-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(1) a licensee with authority to prescribe or administer controlled substances:

(a) prescribing or administering to himself any Schedule II or III controlled substance [~~which~~]that is not lawfully prescribed by another licensed practitioner having authority to prescribe the drug;

(b) prescribing or administering a controlled substance for a condition he is not licensed or competent to treat;

(2) violating any federal or state law relating to controlled substances;

(3) failing to deliver to the Division all controlled substance license certificates issued by the Division to the Division upon an action [~~which~~]that revokes, suspends or limits the license;

(4) failing to maintain controls over controlled substances [~~which~~]that would be considered by a prudent practitioner to be effective against diversion, theft, or shortage of controlled substances;

(5) being unable to account for shortages of any controlled substance inventory for which the licensee has responsibility;

(6) knowingly prescribing, selling, giving away, or administering, directly or indirectly, or offering to prescribe, sell, furnish, give away, or administer any controlled substance to a drug dependent person, as defined in Subsection 58-37-2(1)(s), except for legitimate medical purposes as permitted by law;

(7) refusing to make available for inspection controlled substance stock, inventory, and records as required under this rule or other law regulating controlled substances and controlled substance records;

(8) failing to submit controlled substance prescription information to the database manager after being notified in writing to do so.

R156-37-603. Restrictions Upon the Prescription, Dispensing and Administration of Controlled Substances.

(1) A practitioner may prescribe or administer the Schedule II controlled substance cocaine hydrochloride only as a topical anesthetic for mucous membranes in surgical situations in which it is properly indicated and as local anesthetic for the repair of facial and pediatric lacerations when the controlled substance is mixed and dispensed by a registered pharmacist in the proper formulation and dosage.

(2) A practitioner shall not prescribe or administer a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

(3) [~~When writing a prescription for a controlled substance, each prescription shall contain only one controlled substance per prescription form and no other legend drug or prescription item shall be included on that form.~~

~~(4)~~]In accordance with Subsection 58-37-6(7)(f)(v)(D), unless the prescriber determines there is a valid medical reason to allow an earlier dispensing date, the dispensing date of a second or third prescription shall be no less than 30 days from the dispensing date of the previous

prescription, to allow for receipt of the subsequent prescription before the previous prescription runs out.

([~~5~~]4) If a practitioner fails to document his intentions relative to refills of controlled substances in Schedules III through V on a prescription form, it shall mean no refills are authorized. No refill is permitted on a prescription for a Schedule II controlled substance.

([~~6~~]5) Refills of controlled substance prescriptions shall be permitted for the period from the original date of the prescription as follows:

(a) Schedules III and IV for six months from the original date of the prescription; and

(b) Schedule V for one year from the original date of the prescription.

([~~7~~]6) No refill may be dispensed until such time has passed since the date of the last dispensing that 80% of the medication in the previous dispensing should have been consumed if taken according to the prescriber's instruction.

([~~8~~]7) No prescription for a controlled substance shall be issued or dispensed without specific instructions from the prescriber on how and when the drug is to be used.

([~~9~~]8) Refills after expiration of the original prescription term requires the issuance of a new prescription by the prescribing practitioner.

([~~10~~]9) Each prescription for a controlled substance and the number of refills authorized shall be documented in the patient records by the prescribing practitioner.

([~~11~~]10) A practitioner shall not prescribe or administer a Schedule II controlled stimulant for any purpose except:

(a) the treatment of narcolepsy as confirmed by neurological evaluation;

(b) the treatment of abnormal behavioral syndrome, attention deficit disorder, hyperkinetic syndrome, or related disorders;

(c) the treatment of drug-induced brain dysfunction;

(d) the differential diagnostic psychiatric evaluation of depression;

(e) the treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants or MAO inhibitors;

(f) in the terminal stages of disease, as adjunctive therapy in the treatment of chronic severe pain or chronic severe pain accompanied by depression;

(g) the clinical investigation of the effects of the drugs, in which case the practitioner shall submit to the Division a written investigative protocol for its review and approval before the investigation has begun. The investigation shall be conducted in strict compliance with the investigative protocol, and the practitioner shall, within 60 days following the conclusion of the investigation, submit to the Division a

written report detailing the findings and conclusions of the investigation; or

(h) in treatment of depression associated with medical illness after due consideration of other therapeutic modalities.

([~~12~~]11) A practitioner may prescribe, dispense or administer a Schedule II controlled stimulant when properly indicated for any purpose listed in Subsection ([~~11~~]10), provided that all of the following conditions are met:

(a) before initiating treatment utilizing a Schedule II controlled stimulant, the practitioner obtains an appropriate history and physical examination, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized;

(b) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant when he knows or has reason to believe that a recognized contraindication to its use exists;

(c) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant in the treatment of a patient who he knows or should know is pregnant; and

(d) the practitioner shall not initiate or shall discontinue prescribing, dispensing or administering all Schedule II controlled stimulants immediately upon ascertaining or having reason to believe that the patient has consumed or disposed of any controlled stimulant other than in compliance with the treating practitioner's directions.

R156-37-606. Disposal of Controlled Substances.

(1) Any disposal of controlled substances by licensees shall[~~:~~ ~~(a)~~] be consistent with the provisions of 1307.21 of the Code of Federal Regulations[~~; or~~

~~(b) require the authorization of the Division after submission to the Division to the attention of Chief Investigator of a detailed listing of the controlled substances and the quantity of each. Disposal shall be conducted in the presence of one of its investigators or a Division authorized agent as is specifically instructed by the Division in its written authorization~~].

(2) Records of disposal of controlled substances shall be maintained and made available on request to the Division or its agents for inspection for a period of five years.

KEY: controlled substances, licensing
Date of Enactment or Last Substantive Amendment: [~~January 8, 2013~~]2015
Notice of Continuation: February 21, 2012
Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-37-6(1)(a); 58-37f-301(1)